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ASSOCIATION OF AMERICAN RAILROADS

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April 25, 2003

Food and Drug Administration  
Dockets Management Branch  
5630 Fishers Lane rm. 1061  
Rockville, MD 20852

Re: Docket No. 02N-0278 Prior notice of imported food under the  
Public Health Security and Bioterrorism Preparedness and  
Response Act of 2002

Dear Sir or Madam:

Enclosed are the comments of the Association of American Railroads for Docket  
No. 02N-0278.

Respectfully submitted,

Enclosure

02N-0278

C219

BEFORE THE  
FOOD AND DRUG ADMINISTRATION

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DOCKET NO. 02N-0278  
PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY  
AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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COMMENTS OF  
THE ASSOCIATION OF AMERICAN RAILROADS

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The Association of American Railroads (AAR),<sup>1</sup> on behalf of itself and its member railroads, submits these comments in response to the notice of proposed rulemaking in which FDA proposes to require U.S. purchasers or U.S. importers or their agents to submit to FDA prior notice of the importation of food.<sup>2</sup>

The purpose of this rulemaking proceeding is to implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) that require prior notification of imported food and require FDA to issue final regulations that specify the period of advance notice by December 12, 2003. FDA states in the notice of proposed rulemaking that this rule would

enhance FDA's ability to inspect imported food when it arrives in the U.S. This in turn would result in a significant improvement in FDA's ability to deter, prepare for, and respond effectively to bioterrorism and other public health emergencies that might result from imported food.<sup>3</sup>

AAR's member railroads, who operate in the U.S., Canada, and Mexico, and account for the vast majority of rail transportation across the Mexican and Canadian borders, are concerned that application of FDA's proposed prior notification rule for the importation of food would adversely affect the ability of the rail industry to efficiently transport food into the U.S. FDA should consider existing transborder rail operations, border system functionality, and the transactional process between railroads, Customs, and rail shippers in order to ensure the continued smooth flow of trade at our northern and southern borders.

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<sup>1</sup> AAR is a trade association whose membership includes freight railroads that operate 77 percent of the line-haul mileage, employ 91 percent of the workers, and account for 94 percent of the freight revenue of all railroads in the United States; and passenger railroads that operate intercity passenger trains and provide commuter rail service.

<sup>2</sup> See 68 Fed. Reg. 5428 (February 3, 2003).

<sup>3</sup> 68 Fed. Reg. 5429.

## I. Key Principles of Rail Operations

As FDA considers how best to implement the Bioterrorism Act's prior notice requirements, it is important to recognize the distinctive nature of cross-border rail operations. North American railroads provide three major types of cross-border rail transportation service:

1. Traffic originated at rail hubs -- these trains of carload or domestic intermodal shipments are assembled at major rail yards for movement across the border.
2. Rail traffic that is picked up by transborder trains en route to the border -- such traffic generally is high-volume traffic that is considered low-risk from a security standpoint.
3. International intermodal shipments that arrive by container vessel at Canadian ocean ports for movement to the United States.

A small number of rail carriers provide cross-border rail transportation service and account for the more than one-hundred trains that cross the borders daily. In addition to the seven largest North American rail carriers (*i.e.*, the Class I carriers), several short-line carriers are involved in cross-border transportation.

There are distinctions between cross-border rail operations at the U.S./Canada and U.S./Mexico borders. At the U.S./Canada border, a single rail carrier operating on both sides of the border will typically assemble and handle a train from points within the United States or Canada for movement across the border. At the U.S./Mexico border, a train often is interchanged between U.S. and Mexican carriers at the border crossing point.

The entire North American system of Class I railroads is a continuous bonded network. Information on rail shipments is electronically communicated between rail carriers through an interchange protocol that is governed by AAR rules. This North American infrastructure allows for any rail conveyance to be trapped in the rail "pipeline" until authorized for delivery to the consignee. Currently, the Bureau of Customs and Border Protection (CBP) and the U.S. Department of Agriculture (USDA) manage requests for examination, release, and delivery authorization to rail carriers through the Rail Automated Manifest System (AMS) hold and release process.

The rail industry is, for the most part, highly automated. Due to the wide participation by carriers in AMS, electronic manifest information (information on individual rail cars) for the vast majority of rail traffic crossing at the U.S. borders is transmitted to CBP (in a 309 transmission) well in advance of the arrival of those cars at a border. The preliminary manifest information is currently available to CBP in AMS almost immediately after the rail carriers receive the bill of lading information from the rail shipper. Information on arrival times is transmitted to CBP by the railroads (through the transmission of consist data in a 358 transmission) one hour prior to a train's arrival at

the border. AMS functionality will be preserved through the development and implementation of the Automated Commercial Environment (ACE).

In addition to the generally high level of security associated with rail operations, the railroad industry has undertaken specific security-related activities in the wake of the terrorist attacks of September 11, 2001. Under the auspices of AAR, the industry created five task forces – dealing with information technology and communications; physical infrastructure; operations; hazardous materials; and military movements – to develop a thorough risk analysis of the industry and to develop a comprehensive plan for dealing with those risks. Every major railroad participated in this endeavor, with assistance from outside security experts as well. Analysts examined and prioritized all rail assets, identified vulnerabilities, and defined threats in order to assess the risks. The teams then developed more than 100 countermeasures to strengthen security.

The railroad industry's security plan establishes four alert levels and describes a progressive series of actions to thwart terrorist threats to railroad personnel and facilities. It includes additional countermeasures that will be applied in the areas of operations; information technology and communications; and police. The industry also has established an operations center to coordinate railroad security on a 24/7 basis.<sup>4</sup>

## II. Transborder Rail Operations

Rail companies, as importing carriers, have a fully developed electronic process with CBP through AMS that has played an important role in addressing congestion issues at rail points of entry into the U.S. This system has provided effective tools to government agencies for import control and necessary targeting of shipments. The value of AMS for border management is underscored by the commitment from CBP, through the Trade Support Network process, to preserve this system functionality through the development and implementation of ACE.

Transborder rail operations in the electronic environment reflect both rail/shipper industry processes and border authority agency processes. Shippers, rail carriers, and government agencies interact in closely orchestrated time frames in respect to the exchange of data, automated communication protocols, and automated event trigger points. Typically, rail cars that enter the U.S. on one customs bonded railroad subsequently are transported by other customs bonded railroads. Controls in the handling and delivery of rail shipments work well because of the closed operating environment that is the North American rail network and because of the system connectivity between the railroads and CBP. Conversely, railroads and their shippers would be adversely

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<sup>4</sup>CBP has announced that it plans to install Vehicle and Cargo Inspection Systems (VACIS) at major northern rail border crossings to conduct non-intrusive inspections of the contents of railcars and intermodal equipment; such equipment currently is in operation at southern border crossings. The use of this equipment will result in the screening of the vast majority of all transborder rail shipments.

affected if FDA did not take advantage of the rail network and integrated electronic links to address import issues.

Trains moving from terminals, or hubs, outside of the U.S. to terminals inside the U.S. carry a wide range of commodities for a very diverse customer base. A transborder train that can be up to ten thousand feet in length often is made up of rail cars tendered from a multitude of shippers, many of which may be shipping food products. These trains often carry just-in-time goods such as automotive shipments and intermodal shipments, the latter of which can include foreign and domestic originated containers. Domestic rail intermodal customers are often third party logistics companies, in which case there is no direct relationship between the rail carrier and the actual shipper or consignee.

The automated rail customs clearance process is driven by the rail shipper's bill of lading and ties in the rail shipper's data, railroad data, and broker data through AMS. The AMS process typically takes place in a four-hour window prior to a train arriving at the U.S. border. The U.S. purchaser of the goods and its broker do not participate in the rail border process and often have no relationship with the importing rail carrier. Further, in an environment highly dependant on automated processes, there is no systematic way for U.S. importers to ascertain the time it will take from the tendering of a load to a railroad at a foreign origin to arrival of the train at the border.

FDA should ensure that U.S. importers of goods transported by rail can be regularly compliant with the prior notice requirements it ultimately promulgates. Some of the information FDA contemplates requiring is only available to the purchaser's broker at the time that the broker files entry with CBP, which typically takes place within the four-hour window prior to a train's arrival at the border. Additionally, many bulk rail shipments of food products such as grains, legumes, glucose/fructose, etc., are released using Automated Line Release, otherwise known as BRASS releases. The requirement for prior notification in relation to the port of arrival, if significantly different from the notice already given CBP, could greatly dilute the efficiencies of the BRASS system, utilized by rail carriers and repetitive shippers to maintain fluidity at highly congested rail ports of entry.

### III. Relationship to Other Government-Imposed Prior Notice Requirements

FDA seeks comments on the extent to which FDA's proposed prior notice requirements would result in the submission of duplicative prior notice information to more than one federal agency. AAR believes that FDA's proposed rule to require prior notice of food shipments into the United States should be considered in the context of advance notice requirements to be imposed by CBP in two respects: (1) the time frame for submission of this information; and (2) the method for transmitting this information to FDA.

Under Section 343 of the Trade Act of 2002 (Pub. L. No. 107-210), as modified by Section 108(b) of the Maritime Transportation Security Act of 2002 (Pub. L. No. 107-

295), the Department of Homeland Security is authorized to promulgate regulations providing for the transmission to CBP, through an electronic interchange system, of information pertaining to cargo to be imported or exported via modes other than ocean carriers, prior to the arrival or departure of the cargo. The cargo information required by these regulations shall be such information as determined to be reasonably necessary to ensure cargo safety and security pursuant to those laws enforced and administered by CBP. The target date for promulgation of the regulations is October 1, 2003.

CBP issued "strawmen" proposals for the advance cargo information requirements for inbound and outbound rail traffic, which served as a basis for discussion at a public meeting convened by CBP on January 21, 2003, in Washington, D.C. These advance submission requirements pertain to the manifest information submitted to CBP. At CBP's request, the Treasury Advisory Committee on Commercial Operations of the U.S. Customs Service (COAC) submitted recommendations on April 4, 2003, to CBP for advance notice requirements for each mode. For rail carriers, COAC recommended that rail carriers be required to submit data electronically to CBP four hours in advance of a train's arrival at the border, with the exception of truck-competitive traffic, traffic picked up by the rail carrier following a train's departure from a rail hub en route to the border, and certain types of "hybrid" rail traffic. For these latter categories of traffic, COAC recommended a one-hour advance notice requirement.

It is important to recognize the distinction between manifest and train consist information. While COAC recommended a four hour minimum notice requirement for manifest information for most rail cars, the railroads still would be able to ensure that train consist information (information on the rail cars making up a train) is submitted to Customs only one hour in advance of arrival at the border. Less time is available for train consist information than for manifest information because trains often pick up rail cars on the way to the border. The manifest information for these cars is available before the cars are added to the train. Indeed, today railroads submit final train consist information to Customs only one hour prior to a train's arrival at a border (in a 358 transmission).

Thus, FDA's proposal that prior notice be submitted to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing is inconsistent with the current procedures utilized by Customs and the railroad industry and likely will be inconsistent with the advance notice requirements that CBP will be issuing pursuant to the Trade Act of 2002. Consequently, the FDA proposal potentially will have a significant negative impact on international commerce.

Insofar as the process for submitting information is concerned, FDA is proposing that prior notice information be submitted electronically to FDA through the agency's web-based Prior Notice System, which currently is under development with an anticipated completion date of no later than October 12, 2003. FDA notes that it has consulted with CBP about this proposed rule and the possibility of CBP modifying ACS to accommodate the new FDA prior notice requirement, but that CBP determined that ACS could not be modified to accommodate the data requirements of the FDA prior notice regulation by the December 12, 2003, statutory deadline.

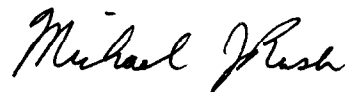
It is imperative that advance data requirements be coordinated among U.S. federal agencies. While the proposed rule states FDA's intention to allow prior notice to be submitted through ACE when it is fully operational, which is anticipated to be no earlier than 2005, AAR is concerned about the need to file duplicative information in the interval between the effective date of the FDA regulations and final implementation of ACE.

AAR believes FDA's objectives could be met by using the existing AMS links with rail carriers for transmitting information and the railroads' closed transportation environment to manage holds, releases, and examinations at rail yards within the U.S. In fact, there are communication protocols already in place between USDA and CBP that allow USDA to take advantage of the AMS process, and USDA and CBP easily manage holds, releases, and examinations. Departure from the existing systems runs the risk of severely disrupting international commerce.

#### IV. Conclusion

AAR and its member railroads would welcome the opportunity to separately and concurrently work with FDA to achieve the objectives outlined in the notice of proposed rulemaking. We urge FDA to ensure that the advance data requirements of different federal agencies are not inconsistent or duplicative and that the time frames for the submission of these data are coordinated so that these requirements will not unduly restrict the smooth flow of commerce between the U.S. and its trading partners. The need to enhance security and the need to facilitate international commerce are compatible goals.

Respectfully submitted,



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